

REMARKS**INTRODUCTION**

In accordance with the foregoing, claims 1-24 have been cancelled and claims 25-62 have been added. No new matter is being presented, and approval and entry are respectfully requested.

Claims 25-62 are pending and under consideration. Reconsideration is respectfully requested.

NEW CLAIMS 25-62

New claims 25-31 correspond substantially to claims 1-7, respectively, which have been cancelled. New claims 40-42 correspond substantially to claims 8-10, respectively, which have been cancelled. New claims 43-47 correspond substantially to claims 19-23, respectively, which have been cancelled. New claims 48-49 correspond substantially to claims 11-12, respectively, which have been cancelled. New claims 51-62 correspond substantially to claims 13-24, which have been cancelled. New dependent claims 32-39 and 50 have been added to set forth the invention in varying scope and are believed to patentably distinguish over the prior art for at least those reasons as the independent claims from which they depend. Support for new claims 32-39 can be found, by example, in the originally filed Specification, at least at page 24, line 3 to page 25, line 8. Support for new claim 50 can be found in claim 11, which has been cancelled.

ALLOWABLE SUBJECT MATTER

In the Office Action at page 7, numbered item 7, claims 19-23 were indicated as allowable. As new claims 43-47 and 57-61 correspond substantially to claims 19-23, Applicants respectfully submit that claims 43-47 and 57-61 are also allowable.

REJECTION UNDER 35 U.S.C. §102(b)

In the Office Action at page 2, numbered item 3, claims 1-2 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,781,200 to Baker. This rejection is traversed and reconsideration is respectfully requested.

New independent claim 25 corresponds substantially to rejected independent claim 1. New independent claim 26 corresponds substantially to rejected dependent claim 2, and depends directly from new independent claim 25.

New independent claim 25 is directed to an apparatus for detecting the heart rate of a fetus. In relevant part, the apparatus includes "a detector to detect heart beats of the fetus, the detector including at least two electrodes for detecting ECG signals, and the detector being positioned on the abdomen of the mother in use," and "a processor, coupled to the detector, to process the ECG signals received from the detector and determine the heart rate of the fetus." The processor includes "means for detecting heart beats of the mother by determining when the ECG signals reach a maximum," and "means for determining the heart rate by determining the time interval between adjacent heart beats, so as to determine the heart rate of the mother."

At page 2, the Office Action asserts that Baker at col. 5, lines 1-5, teaches that a plurality of fetal monitoring sensors 35 may be ECG sensors. Further, at page 3, the Office Action asserts that "The control unit of Baker has the ability to determine the heart rate of the mother, because the maternal ECG is detected and processed in order to obtain the fetal heart rate when the fetal heart sensors 35 are ECG sensors." Baker at col. 8, lines 20-40, is cited in support of this assertions. Applicants, however, respectfully disagree.

Baker at col. 8, lines 22-25, states "When fetal heart sensors 35 are electrocardiographic type sensors then the principal noise or interfering signal is from the electrocardiographic (ECG) potential variations occurring within the mother." Further, Baker at col. 8, lines 25-32 states "The signal processing circuitry 100 can be used to adaptively cancel such interference using an interfering or cancelling signal which is predominantly composed of maternal ECG." "This can be done using interfering electrodes placed adjacent to the maternal heart in an arrangement well known in connection with obtaining human electrocardiograms (not shown)."

Thus, Baker considers the maternal heartbeat to be "principal noise" or an interfering signal. Further, Baker teaches that the maternal heartbeat is cancelled out with the use of interfering electrodes (col. 8, lines 29-30). Independent claim 25, in contrast to the teachings of Baker, recites that the processor includes "means for detecting heart beats of the mother by determining when the ECG signals reach a maximum" and "means for determining the heart rate by determining the time interval between adjacent heart beats, so as to determine the heart rate of the mother." Thus, according to the present invention, unlike Baker, the heart beat and heart rate of the mother are detected and used by the processor. Baker, in contrast, only cancels this "noise" out.

For at least these reasons, Applicants respectfully submit that Baker fails to teach or suggest all of the features of new independent claim 25, and those claims depending directly or indirectly therefrom. Accordingly, Applicants respectfully submit that independent claim 25, and those claims depending directly or indirectly therefrom, patentably distinguish over the prior art and are in condition for allowance.

Rejection Under 35 U.S.C. § 103(a)

In the Office Action at page 3, claim 3-18 and 24 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,781,200 to Baker in view of "Lead systems for the abdominal fetal electrocardiogram" A van Oosterom, Clin. Phys. Physiol. Meas., 1989, Vol. 10, Suppl. B, 21-26.

As noted above, new claims 27-31, 40-42, 48-56, and 62 correspond substantially to the rejected claims. Claims 27-31 and 40-42 depend, either directly or indirectly, from independent claim 25, which corresponds to original claim 1. Claims 49-62 depend, either directly or indirectly from new independent claim 48, which corresponds substantially to original claim 11.

As noted above, Applicants respectfully submit that Baker fails to teach or suggest all of the features of independent claim 25. van Oosterom, which was relied upon in the Office Action to cure the deficiencies of Baker, is directed to lead systems for the abdominal fetal electrocardiogram (FECG). van Oosterom, however, fails to cure the deficiencies of Baker with respect to independent claim 25. Thus, Applicants respectfully submit that Baker and van Oosterom, taken alone or in combination, fail to teach or suggest all of the features of dependent claims 27-31 and 40-42. Accordingly, Applicants respectfully submit that claims 27-31 and 40-42 patentably distinguish over the prior art for at least those reasons as independent claim 25 and, thus, are in condition for allowance.

At page 4 of the Office Action, with respect to claims 4-5 (now claims 28-29), the Office Action asserts that "the control unit 40 of Baker includes a visual display (73) of fetal heart rate and can further display other information such as patient history" (citing Baker at col. 6, lines 57-65). Claim 28, however, recites that the processor "generates virtual ECG signals as a weighted sum of the ECG signals detected by the detectors, the virtual ECG signals representing the ECG signals that would have been obtained from a virtual detector positioned at a virtual location on the abdomen of the mother." Claim 29 depends directly from claim 28. Baker, however, fails to teach or suggest the generation of any "virtual ECG signals as a weighted sum of the ECG signals detected by the detectors," as recited in claim 28. van Oosterom is not alleged to cure these deficiencies of Baker. For at least this reason, and those set forth above, Applicants respectfully submit that Baker and van Oosterom, taken alone or in combination, fail to teach or suggest all of the features of dependent claims 28 and 29 and, therefore, claims 28 and 29 are in condition for allowance.

With respect to claim 8, which corresponds substantially to claim 40, the Office Action asserts that Baker teaches determining the heart rate of the fetus by suppressing the maternal signal (citing col. 8, lines 20-40). Claim 40 recites that the processor determines the heart rate of the fetus from the ECG signals by "suppressing portions of the ECG signals representative of the heart beat of the mother." Baker at col. 8, lines 29-32, in contrast, teaches "interfering electrodes placed adjacent to the maternal heart in an arrangement well known in connection with obtaining human electrocardiograms (not shown)." Thus, Baker does not teach suppression of the maternal signal using the same detector for the fetal heart beat, as in the present invention. Instead, Baker teaches that additional, special ECG sensors are required to provide an interference or cancelling signal to cancel out the maternal signal.

Independent claim 11 has been cancelled and rewritten as new independent claim 48. At page 5 of the outstanding Office Action, it is asserted that "Baker teaches an ambulatory non-invasive fetal monitoring system, and thus incorporates the monitoring sensors into a belt that fits around the mother." The Office Action, however, acknowledges that "Baker fails to specifically disclose 'determining the position of the fetus within the womb' and placing the ECG detector 'in accordance with the position of the fetus' because the sensor belt is simply placed around the mother in a predetermined fashion." The Office Action asserts that, in different medical environments, "the sensors of Baker may simply be placed onto the abdomen of the mother rather than incorporating the sensors into a belt." Applicants respectfully disagree. If the sensors of Baker were simply placed onto the abdomen of the mother, Baker would no longer teach an ambulatory non-invasive automatic fetal monitoring system. Rather, Baker incorporates these sensors into a garment that can be worn by the mother, without regard to the position of the sensors with respect to the fetus.

At pages 5-6, the Office Action asserts that "It is well known in the art to position ECG sensors in accordance with the position of the fetus," citing van Oosterom at page 21. Applicants note that the Introduction of van Oosterom explains that the patterns of electronic potentials at the maternal abdomen are "shaped significantly by the position and orientation of the fetal hear with respect to the maternal abdomen." van Oosterom also explains the difficulties which arise as a result of the fetus changing position. Neither Baker nor van Oosterom teach or suggest any solution to these difficulties.

At page 6, the Office Action asserts that "It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to position ECG sensors in accordance with the position of the fetus in order to obtain the strongest and most accurate fetal ECG signals." Applicants respectfully disagree and note that "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Baker speaks to the desirability of integration of sensors into a garment worn by a mother for properly and conveniently wearing the sensors. Baker does not teach or suggest a garment that is adaptable to be placed according to the position of the fetus in order to obtain the strongest and most accurate fetal ECG signals, but instead teaches that sensors are positioned in a garment which is conveniently worn by a mother, without regard to fetal positioning. Thus, Applicants respectfully submit that Baker teaches away from the positioning of ECG sensors in accordance with the position of the fetus.

MPEP 2143.01 states that "If [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Applicants respectfully submit that if the teachings of Baker were modified so that ECG sensors were positioned in accordance with the position of the fetus, the invention of Baker would be unsatisfactory for its intended purpose, as fetal movement would, at a minimum, necessitate alteration of the position of the sensors in the garment of Baker, based on fetal position. Thus, if Baker were modified in the manner proposed, the convenience and ease of use desired by Baker would be lost.

For at least these reasons, Applicants respectfully submit that there is no motivation to combine Baker and van Oosterom. Thus, Applicants respectfully submit that independent claim 48 patentably distinguishes over the prior art and is in condition for allowance.

As the rejections of those claims depending from independent claim 11 (now claim 48) fail to cure the deficiencies of Baker and van Oosterom, Applicants respectfully submit that claims 49-62, which depend directly or indirectly from independent claim 11, patentably distinguish over the prior art for at least those reasons as independent claim 48 and, therefore, are in condition for allowance.

CONCLUSION

In accordance with the foregoing, it is respectfully submitted that all outstanding objections and rejections have been overcome and/or rendered moot. And further, that all pending claims patentably distinguish over the prior art. Thus, there being no further outstanding objections or rejections, the application is submitted as being in condition for allowance which action is earnestly solicited.

If the Examiner has any remaining issues to be addressed, it is believed that prosecution can be expedited by the Examiner contacting the undersigned attorney for a telephone interview to discuss resolution of such issues.

If there are any underpayments or overpayments of fees associated with the filing of this Amendment, please charge and/or credit the same to our Deposit Account No. 19-3935.

Respectfully submitted,

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